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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,464	10/17/2003	Ricardo J. Moro	MORO-1 CONT III	3062

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,464	MORO, RICARDO J.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-39 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claim 1 links inventions 1-22. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1, 3, 6-7, 9, 15, 16, 17 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the antibodies are radiolabeled, classified in Class 424, subclass 130.1, Class 436, subclass 504.

Group 2. Claims 1-3, 6-8, 15, 16, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are

radiolabeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.1, Class 436, subclass 504.

Group 3. Claims 1-3, 6-8, 15, 16, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are radiolabeled, wherein the sample is a smear, classified in Class 435, subclass 7.1, Class 436, subclass 504.

Group 4. Claims 1, 4, 10, 11, 13, 15-17 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the antibodies are enzyme labeled, classified in Class 424, subclass 130.1, Class 436, subclass 503.

Group 5. Claims 1, 2, 4, 10, 11, 12, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 6. Claims 1, 2, 4, 10, 11, 12, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 7. Claims 1, 2, 4, 10, 11, 13, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme

labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 8. Claims 1, 2, 4, 10, 11, 13, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 9. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the antibodies are fluorochrome labeled, classified in Class 424, subclass 130.1, Class 436, subclass 503.

Group 10. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are fluorochrome labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 11. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled antibodies to AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are fluorochrome labeled, wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 12. Claims 1, 3, 6-7, 9, 15, 16, 17 are drawn to detecting cancer in a patient comprising introducing labeled AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the

antibodies are radiolabeled, classified in Class 424, subclass 130.1, Class 436, subclass 504.

Group 13. Claims 1-3, 6-8, 15, 16, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are radiolabeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.1, Class 436, subclass 504.

Group 14. Claims 1-3, 6-8, 15, 16, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are radiolabeled, wherein the sample is a smear, classified in Class 435, subclass 7.1, Class 436, subclass 504.

Group 15. Claims 1, 4, 10, 11, 13, 15-17 are drawn to detecting cancer in a patient comprising introducing labeled AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the antibodies are enzyme labeled, classified in Class 424, subclass 130.1, Class 436, subclass 503.

Group 16. Claims 1, 2, 4, 10, 11, 12, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 17. Claims 1, 2, 4, 10, 11, 12, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled,

wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 18. Claims 1, 2, 4, 10, 11, 13, 15-18, 20 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 19. Claims 1, 2, 4, 10, 11, 13, 15-17, 19 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are enzyme labeled, wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 20. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled AFP to a biological sample of the patient, wherein the biological sample is in the patient, wherein the antibodies are fluorochrome labeled, classified in Class 424, subclass 130.1, Class 436, subclass 503.

Group 21. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the patient wherein the antibodies are fluorochrome labeled, wherein the sample is a tissue section, classified in Class 435, subclass 7.21, Class 436, subclass 503.

Group 22. Claims 1, 5, 14-17 are drawn to detecting cancer in a patient comprising introducing labeled AFP, *in vitro*, to a biological sample of the

patient wherein the antibodies are fluorochrome labeled, wherein the sample is a smear, classified in Class 435, subclass 7.21, Class 436, subclass 503.

4. Claim 21 links inventions 23-30. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 23. Claims 21-24, 27-29, 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are conjugated to drugs, wherein the antibodies are monoclonal or polyclonal produced *in vitro* from lymphocytes of the same species as the patient, classified in Class 424, subclass 130.1, Class 435, subclass 503.

Group 24. Claims 21-24, 27-29, 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are conjugated to drugs, wherein the antibodies are

monoclonal or polyclonal from a species different than said patient, classified in Class 424, subclass 130.1, Class 435, subclass 503.

Group 25. Claims 21-24, 27-29, 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are conjugated to toxins, wherein said antibodies are produced *in vitro* from lymphocytes of the same species as the patient, classified in Class 424, subclass 130.1, Class 435, subclass 503.

Group 26. Claims 21-24, 27-29, 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are conjugated to toxins, wherein said antibodies are monoclonal or polyclonal from a species different than said patient, classified in Class 424, subclass 130.1, Class 435, subclass 503.

Group 27. Claims 21-24, 27-28, 30-31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are radiolabeled, wherein said antibodies are produced *in vitro* from lymphocytes of the same species as the patient classified in Class 424, subclass 130.1, Class 435, subclass 504.

Group 28. Claims 21-24, 27-28, 30-31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein the antibodies are radiolabeled, wherein said antibodies are monoclonal or polyclonal from a species different than said patient classified in Class 424, subclass 130.1, Class 435, subclass 504.

Group 29. Claims 21, 25-26 , 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein said antibodies are produced *in vitro* from lymphocytes of the same species

as the patient, as well as AFP receptor of a species different from the patient in order to stimulate autologous antibodies to said AFP receptor as well as , classified in Class 424, subclass 130.1 and Class 514, subclass 2+.

Group 30. Claims 21, 25-26 , 31 are drawn to a method of treating cancer cells in a patient comprising administering AFP receptor antibodies, wherein said antibodies are monoclonal or polyclonal from a species different than said patient, as well as AFP receptor of a species different from the patient in order to stimulate autologous antibodies to said AFP receptor as well as , classified in Class 424, subclass 130.1 and Class 514, subclass 2+.

Group 31. Claim 32 is drawn to a method for monitoring a patient comprising treating the patient for cancer and testing the patient at predetermined intervals for AFP receptor site levels, classified in Class 435, subclass 7.1

5. Claim 33 links inventions 32-33. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 33. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions

of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 32. Claim 33 is drawn to a method of treating a patient comprising testing the patient for AFP receptor, introducing AFP receptor antibodies into the patient, classified in Class 435, subclass 7.1 and Class 424, subclass 130.1.

Group 33. Claim 33 is drawn to a method of treating a patient comprising testing the patient for AFP receptor, introducing AFP into the patient, classified in Class 435, subclass 7.1 and Class 514, subclass 2+.

Group 35. Claims 34-39 are drawn to a method of treating a cancer cells in a patient comprising introducing modified AFP to cancer cells in the patient, classified in Class 514 subclass 2+.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-35 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 872-9306.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
June 8, 2004